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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,570	09/09/2003	Martin Morrissey	MCA-616 US	5746
25182	7590	01/24/2008	EXAMINER	
MILLIPORE CORPORATION 290 CONCORD ROAD BILLERICA, MA 01821			MCKANE, ELIZABETH L	
			ART UNIT	PAPER NUMBER
			1797	
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			01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/659,570	MORRISSEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leigh McKane	1797	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 November 2007.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,5-13 and 21-23 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2,5-13 and 21-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 09 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All \* b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5, 6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Padgett (US 4,644,586) or Trewella et al. (US 3,073,507).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines 19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed **38** adjacent the interface between the first and second portions to create a sealed, sterile portion. See col.4, lines 10-38; Figures 4-6.

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15. The intended use of the device does not structurally limit the bag in any patentable sense.

As to the recitation of the contents of the bag, it has been held that "expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." See *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Furthermore, as to the contents and the second section being under a vacuum or positive pressure, these limitations are directed to the ultimate intended use of the device and do not limit the bag in any structural manner.

As to claims 5 and 6 and the limitations wherein "the bag and its contents being under a slight vacuum" and "the bag and its contents being under a slight positive pressure" are not considered to be structurally limiting on the bag but are intended uses of the bag.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trewella et al. in view of McDonald (US 6,030,578).

Trewella et al. is silent with respect to a closed collar or port attached to the non-porous

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section. McDonald, however, discloses a container **201** for sterilizing and transferring articles to a sterile enclosure. The container includes a collar **202** for attachment to a sterile enclosure during transferring of the sterilized articles. This collar is certainly capable of use as a pressure or vacuum port, as well. Since the bag of Trewella et al. is disclosed for use in the sterilization of medical articles, it would have been obvious to use the bag of Trewella et al. in the sterile environment of McDonald and when doing so, to provide a collar for connection to the enclosure.

5. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Padgett or Trewella et al., both in view of Massage (US 3,837,215).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines 19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed 38 adjacent the interface between the first and second portions to create a sealed, sterile portion. See col.4, lines 10-38; Figures 4-6.

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15.

Neither Padgett nor Trewella et al. disclose a step of applying a vacuum or a positive pressure to the second section during or after the formation of the second seal. Massage discloses a method of integrity testing of sealed containers. The containers may be flexible packages/bags (col.1, lines 6-18) and are tested under a vacuum or positive pressure holding after being sealed. See col.3, lines 51-57. As Massage discloses that integrity testing assures that the packages are adequately sealed from contaminants and as both Padgett and Trewella et al. teach sealing the sterilized contents from contaminants, it would have been obvious to employ the method of Massage to test the integrity of the seal of the second section.

#### ***Response to Arguments***

6. Applicant's arguments filed 30 July 2007 have been fully considered but they are not persuasive.
7. Applicant argues that neither Padgett nor Trewella et al. disclose maintaining the second section in a condition of a vacuum or positive pressure. However, as set forth in the rejection, this type of limitation is no more than an intended use of the bag and does not structurally limit the invention. In fact, Applicant seems to be arguing the limitations of the article of manufacture as illustrated in Figure 2 of the instant invention. If Applicant intends to claim the sealed transfer bag *in combination with* the sterilized articles located therein, wherein the sealed transfer bag is under pressure or vacuum, then the article of manufacture itself should be claimed. As it stands, the instant claims are either article claims drawn to a bag or a process of using the bag.
8. With respect to the combination with MacDonald, Applicant asserts that the application of a port to the bags of Padgett and Trewella et al. would be "irrelevant and useless." However,

as the port of MacDonald would have permitted the bags of Padgett and Trewella et al. to be securely attached to sterile enclosures for transfer of the sterilized articles, the port would have been neither irrelevant nor useless and moreover, would have produced entirely predictable results.

9. In response to Applicant's arguments that the Examiner has used hindsight to reject the instant claims, the Examiner notes that as indicated by the Supreme Court, any alleged risk of hindsight bias should not be overemphasized so as to defy common sense. See *KSR International Co. v. Teleflex Inc.*, 550 U.S.----, 82 USPQ2d 1385, 1397 (2007). Furthermore, the KSR decision makes clear that the teaching, suggestion, or motivation (TSM) test is not the only rationale that may be relied upon to support a conclusion of obviousness. Regardless, in this case the Examiner has provided motivation for the combination.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Leigh McKane*  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1797**

elm  
21 January 2008